

201-14863



Cytec Industries Inc.
Toxicology & Product Regulatory Compliance Dept.
5 Garret Mountain Plaza
West Paterson, NJ 07424

November 25, 2003

The Honorable Mike Leavitt, Administrator
U. S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

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REFERENCE: Chemical Right-To-Know

Dear Administrator:

Cytec Industries Inc. is pleased to respond to the EPA Comments on the robust summaries and test plan for 6-tert-butyl-3-(chloromethyl)-2,4-xyleneol (CAS No. 23500-79-0) as posted on the Chemical RTK HPV Challenge Program Web site.

The Environmental Protection Agency has reviewed the test plan submission and reached the following conclusions:

- The physicochemical data and test plan presented are adequate for the purposes of the HPV Challenge Program.
- The EPA agrees that the submitter has adequately supported the closed system intermediate claim for the substance and is eligible for reduced testing.
- The Agency agrees with the submitter's test proposal for ecotoxicity and environmental fate
- The EPA concludes that adequate data are available for acute toxicity and bacterial mutagenicity assays, and agrees with the submitter's proposal to test for in vitro chromosomal aberrations and developmental toxicity. Cytec Industries Inc. intends to conduct the in vitro chromosomal aberration study with human lymphocytes.

In addition to the above conclusions the EPA has raised the following two issues:

1. The submitter needs to provide hydrolysis data for the chemical.
2. The EPA points out that the repeated-dose test proposed in the test plan is not necessary, and the Agency suggests that a combined screening test be conducted as an alternative to the developmental toxicity test proposed.

In response to the above issues, Cytex Industries Inc. proposes to amend the test plan to conduct the hydrolysis study following OECD guidelines, and to conduct a combined screening test (OECD Guideline 422). These tests will be in addition to the already agreed upon in vitro chromosomal aberration and ecotoxicity/environmental fate studies. It is our belief that the amended test plan will address the needs of this chemical in accordance to the EPA conclusions, and at the same time reduce the number of animals required for testing in line with animal rights concerns. Testing is being contracted and will be completed in 2004.

We are pleased to work cooperatively with the Agency and other interested parties to complete the screening needs for this substance under the Chemical RTK HPV Challenge Program.

The revised robust summary and test plan is provided as hard copy and .pdf format.

Sincerely,

Randy Deskin, Ph.D., DABT
Director, Toxicology & Product Regulatory Compliance